Compliance Assistance Tool for Clean Air Act Regulations: Subpart GGG of40 CFR NESHAPS for Source Category Pharmaceutical Production

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Office of Enforcement and Compliance Assurance
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Air, Hazardous Waste and Toxics Branch

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LIST OF ACRONYMS

ACT	Alternative Control Techniques Information Document (EPA, 1994)
APCD	Air Pollution Control Device
ASTM	American Society for Testing and Materials
BOD	Biological Oxygen Demand
BP	Boiling Point
CAA	Clean Air Act
CAS Number	Chemical Abstracts Service Number
CEF	Control Equipment Failures
CEMS	Continuous Emissions Monitoring System
CFR	Code of Federal Regulations
CH_4	Methane
CMS	Continuous Monitoring System
CO_2	Carbon Dioxide
CTG	Control Technology Guidelines (EPA, 1978)
CVS	Closed Vent System
CWA	Clean Water Act
DE	Design Evaluation
DOT	Department of Transportation
EC	Air Emissions Control
ED	Estimated Dose
EE	Emissions Estimation
EPC	Emission Potential Concentrations
EPA	U.S. Environmental Protection Agency
F_{bio}	Degradation Factor for biological treatment
Fm	Fraction measured
FDA	Food and Drug Administration
FID	Flame Ionization Detector
FR	Flowrate
gal	Gallon
GC	Gas Chromatography
GGG	subpart GGG to part 63 - NESHAP
H_2O	Water
HAPs	Hazardous Air Pollutants
HCl	Hydrogen Chloride
HDPE	High Density Polyethylene
HON	Hazardous Organic - NESHAP
IDS	Individual Drain System
I&M	Inspection and Maintenance
IWP	Improper Work Practices
Kb	Subpart of NSPS- requirements for storage tanks w/floating roofs
kg	Kilogram

lb	Pound
LDAR	Leak Detection and Repair
M^3	Cubic Meter
M21	Method 21
MACT	Maximum Achievable Control Technology
MDL	Method Detection Limit
MED	Median Effective Dose
MiBK	Methyl isobutyl Ketone
mmHg	millimeters Mercury
MW	megawatts
NAICS	North American Industrial Classification System
NESHAP	National Emission Standard for Hazardous Air Pollutants
NOC	Notification of Compliance
NOCSR	Notification of Compliance Status Report
NPDES	National Pollutant Discharge Elimination System
NSPS	New Source Performance Standards
O_2	Oxygen
O/O	Owner or Operator
P2	Pollution Prevention
Pa	Pascal
PEG	Polyethylene Glycol
PhRMA	Pharmaceutical Research and Manufacturers of America
PL	Production Levels
PMPU	Pharmaceutical Manufacturing Process Unit
POD	Point of Determination
ppm	Parts per million
ppmv	Parts per million volume
ppmw	Parts per million weight
PRV	Pressure Release Valve
PSHAP	Partially Soluble Hazardous Air Pollutants
psi	Pound per Square Inch
PT	Performance Testing
QA/QC	Quality Assistance/Quality Control
RCRA	Resource Conservation and Recovery Act
RE	Removal Efficiences
scfm	standard cubic feet per minute
SHAP	Soluble Hazardous Air Pollutants
SIC code	Standard Industrial Classification
SSM	Startup, Shutdown, or Malfunction
TOC	Total Organic Compounds
tpy	Tons per year
TSS	Total Suspended Solids
TTN	Technology Transfer Network (http://www.epa.gov/ttn/)
VHAP	Volatile Hazardous Air Pollutants
VOC	Volatile Organic Compounds

VP	Vapor Pressure
VS	Vapor Suppression
WMU	Waste Management Unit
WW	Waste Water
WWT	Wastewater Treatment

Chapter 3
Applicability and Compliance Dates

3.1 Overview

The applicability section of the MACT regulations defines what kinds of facilities must comply with the regulations and specifies the dates by which those facilities must comply. It also contains provisions for instances in which the MACT standards overlap other regulatory programs. The applicability provisions of the MACT rule are based on a set of definitions, all of which must be reviewed to determine if the regulations apply at any particular facility. The discussion below takes the reader through a series of questions and relevant definitions.

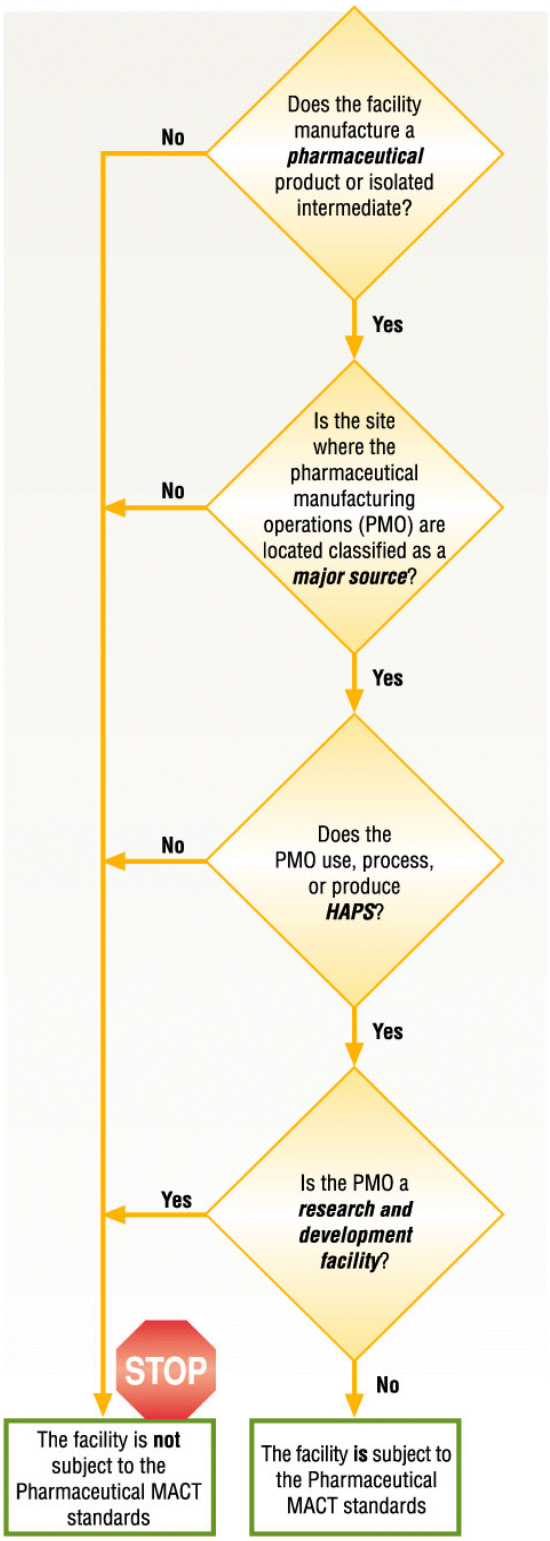
3.2 Applicability

Chapter 3 at a Glance

In general, facilities or activities covered by a National Emissions Standard for Hazardous Air Pollutants (NESHAP) are called "affected sources", which is defined in §63.2. The affected source regulated under Subpart GGG is the pharmaceutical manufacturing operations**,** which is defined in §63.1251. Furthermore, it is important to specifically identify the "affected source" and/or "pharmaceutical manufacturing process unit (PMPU)" because it is the basis for decisions regarding "construction" and "reconstruction," which in turn are the basis for determining whether a facility or manufacturing unit is subject to standards for existing or new sources. Because standards for new sources can be more stringent than those for existing sources, proper identification of the affected source is critical. The applicability regulations provide three criteria that determine whether a facility has pharmaceutical manufacturing operations that are subject to subpart GGG:

- Does the facility manufacture a pharmaceutical product?
- Is the site where the pharmaceutical manufacturing operation is located classified as a major source for HAP emissions?
- Does the pharmaceutical manufacturing operation use, process, or produce HAPs?

The following flow-chart takes the reader through the questions that must be asked to ascertain applicability of the pharmaceutical MACT standards to a specific site.



Pharmaceutical Product =

(1) Any material described by the SIC code 2833 or 2834,
(2) Any material whose manufacturing process is described by North American industrial classification system (NAICS) code 325411 or 325412,
(3) A finished dosage form of a drug, for example, a tablet, capsule, solution, etc.
(4) Any active ingredient or precursor that is produced at a facility whose primary manufacturing operations are described by SIC code 2833 or 2834, or at a facility whose primary operations are not described by SIC code 2833 or 2834, any material whose primary use is as an active ingredient or precursor.

The term does not include nonreactive solvents, binders, fillers, or excipients, but includes components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients. It does not include material produced in a chemical manufacturing unit that is subject to the HON.

Major Source =

Any stationary source or group of stationary sources located within a contiguous area under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tpy or more of any hazardous air pollutant or 25 tpy or more of any combination of hazardous air pollutants. The Administrator may establish a lesser quantity or, in the case of radionuclides, different criteria, for a major source other than that specified in the previous sentence, on the basis of the potency of the air pollutant, persistence, potential for bioaccumulation, other characteristics of the air pollutant, or other relevant factors.

HAP =

Any Hazardous Air Pollutant listed in or pursuant to section 112(b) of the Clean Air Act.

Research and Development Facility =

Any stationary source whose primary purpose is to conduct research and development into new processes and products, where such source is operated under close supervision of technically trained personnel, and is not engaged in the manufacture of products for commercial sale in commerce, except in a de minimis manner.

Figure 3-1. Guidelines for Determining Subpart GGG Applicability

Intermediates

One of the first questions to be asked in making applicability determinations is whether the material being produced is a "pharmaceutical product." The full definition of pharmaceutical product is provided in the flowchart on the previous page. It is important to note that the definition of "pharmaceutical product" includes materials that are not final products, such as precursors or active ingredients. This means that pharmaceutical precursors, even if they are not manufactured at the same site as the final active ingredient, may be covered under the rule.

Exclusions

The term "pharmaceutical product" does **not include** non-reactive solvents, excipients, binders, or fillers. An excipient is a substance, other than the active drug or product, that is used in the drug delivery system to 1) aid the processing of the drug delivery system during manufacture, 2) protect, support or enhance stability, bioavailability, or patient acceptability, 3) assist in product identification, or 4) enhance any other attribute of the overall safety and effectiveness of the drug delivery system during storage or use.

In addition, substances produced in a chemical manufacturing process unit that is already subject to regulation under 40 CFR Part 63, Subparts F and G (SOCMI) are not included in the definition of pharmaceutical product.

Q and A - Example Applicability Scenarios

Q. ***If a chemical specialty company (that is a major source), not principally engaged in pharmaceutical production, receives a chemical compound from an off-site pharmaceutical manufacturer, performs a processing step on the compound, and then ships it back to the original manufacturer, is the chemical specialty company producing a "pharmaceutical product," and potentially subject to the MACT standards?***

A. *The definition of "pharmaceutical product" in the MACT regulations would include the chemical compound in this example. The definition includes active ingredients and precursors that are processed at facilities outside of the 2833 or 2834 SIC code. Such a material is considered a precursor if it has no recognized non-drug commercial use; is used on site; or sold to a pharmaceutical manufacturer, for use in the manufacture of another pharmaceutical product. A precursor is considered a "pharmaceutical product." Clearly, the intermediate in the example is considered a*

product." Clearly, the chemical compound in the example is considered a pharmaceutical product because it is sold back to the pharmaceutical manufacturer. Therefore, the chemical specialty company is subject to the MACT standards, provided it meets the other MACT applicability requirements (e.g, major source for HAPs). It is the responsibility of the chemical specialty company to determine the ultimate use of the chemical compound. For example, the material would not be subject to regulation as a pharmaceutical product if its production is subject to regulation under Subpart F and G for the Synthetic Organic Chemicals Manufacturing Industry (HON). Since it has no non-drug uses, it cannot be a commodity chemical. Chemicals listed in the "Industrial Organic Chemical Use Trees" (Final Report, October 1983, USEPA) are commodity chemicals not regulated under the pharmaceutical MACT. The chemicals listed in Table 1 of Part 63, Subpart F (HON) are not subject to the pharmaceutical MACT.

Q. ***A facility (that is a major source but whose primary SIC code is <u>not</u> 2833 or 2834) makes a product (Product A) that is not pharmacologically active but uses HAP. The Product A is then shipped off-site and reacted with other materials to form a pharmacologically active compound. Product A is not shipped to anyone else or used for any other reactions that the company is aware of. Is the facility making Product A covered under the pharmaceutical MACT?***

A. *Yes; the process would be covered because Product A is a precursor, which is defined as material that undergoes chemical change or processing before it becomes an active ingredient. In this case because the chemical does not have any known non-drug use, its primary use must be as a precursor; therefore it is a pharmaceutical product.*

Q. ***In the making of a pharmaceutical intermediate, a reaction is done to put a blocking agent onto the molecule. Later in the synthesis of the pharmaceutical product, this blocking agent is removed from the pharmaceutical molecule and is discarded. Would the manufacture of the blocking agent be covered under this NESHAP?***

A. *No, because the blocking agent is not subsequently processed into a final drug product. It does not become an active ingredient or other pharmaceutical product covered by SIC 2833 or 2834. The blocking agent does not meet the definition of pharmaceutical intermediate.*

Q. ***If a HON unit produces HCl as a byproduct and further processes a portion of this HCl into "pharmaceutical grade" HCl (the primary use of this HCl is for pharmaceutical manufacturing), is the process subject to the rule?***

A. *No, the HCL is still considered a commodity chemical.*

Q. ***If a toll manufacturer (that is a major source and that uses, processes, or produces HAPs) manufactures a pharmaceutical product, what other sources at the facility (e.g., storage tanks, heat exchange systems, common solvent recovery operations) are covered by the pharmaceutical MACT standards?***

A. *The definition of "pharmaceutical manufacturing operations" includes the facility-wide collection of pharmaceutical manufacturing process units (PMPUs) AND any other equipment (e.g., heat exchangers, wastewater, and waste management units) that are located at a facility manufacturing pharmaceutical products. All equipment used in the manufacture of pharmaceutical products must comply with GGG. For storage tanks, this may imply issues of predominant use. For other sources, issues relating to overlapping MACT standards may be involved.*

Q. ***Are vitamins considered pharmaceutical products?***

A. *Yes, vitamins are considered pharmaceutical products because they are covered by SIC code 2833. Thus their manufacture is subject to the Pharmaceutical Production MACT.*

Q. ***Is the production of artificial sweetener covered by the standard?***

A. *No; the process would not be covered, because it does not meet the definition of pharmaceutical product. Specifically, it is not covered under SIC codes 2833, 2834, and the production is not covered under NAICS codes 325411 or 325412. Additionally, as a food additive that is not covered under SIC 2833 or 2834, it is also not an active ingredient. Finally, it is not a precursor.*

Q. ***Are preparations manufactured for the treatment of animals classified as "pharmaceutical products?"***

A. *Yes; animal biologics (materials used in the treatment of animals) are included in the definition of active ingredients and active ingredients are pharmaceutical product.*

Q. ***Is the production of animal growth hormone covered by the standard?***

A. *Yes; "Hormones and derivatives" are covered by SIC code 2833 and the corresponding NAICS code 325411.*

Q. ***Are all drug ingredients considered pharmaceutical products?***

A. *A substance that* ***meets the definition of excipient*** *is not included in the definition of pharmaceutical product. Generally, excipients are used to enhance the drug delivery system, and include substances such as buffers, flavorings, coloring, and inert binding agents.*

Q. ***Are pilot plants subject to the MACT standards?***

A. *A pilot plant could meet the definition of "research and development facility" if its primary purpose is to conduct research and development into new processes and products, and if it is not engaged in the manufacture of products for commercial sale, except in a de minimis manner. However, if the product being made in an R + D program goes into commercial production, the commercial process becomes subject to the MACT.*

Q. ***Do the regulations apply during start-up and shutdown for batch operations?***

A. *Both batch and continuous operations are subject to SSM requirements. The regulations provide that emission limitations do not apply during periods of start-up, shutdown, and malfunction if the owner or operator follows the plan developed pursuant to §63.1259(a)(3) (or documents and reports deviations from the plan). The owner or operator is required to follow the reporting requirements for periods of start-up, shutdown, or malfunction, as specified in §63.1260(i). However, the definition of shutdown does <u>not</u> apply to the routine cessation of <u>batch</u> operations at the end of a campaign, for routine maintenance, for rinsing or washing equipment between batches, or other routine operations. Shutdown for repairing equipment (if not routine) would count as periods of shutdown. The term start-up applies only to the first time a new or reconstructed source begins production, the first time new equipment is used, or the first time a new product/process is run in equipment. Therefore, the emission limitations **do** apply to start-up and shutdown for batch operations between batches and between most product campaigns, except when non-routine maintenance or repair is necessary.*

Q. ***If a pharmaceutical manufacturing process unit (PMPU) at a facility subject to the MACT standards does not process, use, or produce HAPs or uses HAPs only in de minimis quantities, is the PMPU subject to the MACT standards?***

A. *No, the applicability provisions specify that the regulations apply only to pharmaceutical manufacturing operations that process, use, or produce HAPs. Within the regulated PMO, a process, or a PMPU, that does not process, use, or produce HAP is not subject to the emission standards. Sections 63.1260(f)(1) and (f)(2) indicate that the NOC report must include the results of any applicability determinations and supporting calculations. There is no definition in the regulations for"de minimis." The definitions of process vent, storage tank, and wastewater stream clarify EPA's intent to exclude parts of a plant that do not emit HAPs:*

- *The definition of process vent provides that if uncontrolled, undiluted emissions are less than 50 ppm HAP, the vent is not considered a regulated process vent;*
- *The definition of storage tank provides that a tank that contains HAPs only as impurities is not considered a regulated storage tank;*

- *The definition of wastewater stream includes only those wastestreams with an average concentration of partially soluble and/or soluble HAPs of at least 5 ppmw and a load of at least 0.05 kg/yr.*

3.3 Other Important Applicability Definitions

Other defined terms in the regulations need to be understood for purposes of applicability determinations. Many of these terms can be viewed as a set of nested definitions. The discussion below follows the definitions from "the top down."

Once a facility owner or operator has determined that the facility meets the basic applicability criteria as outlined in 3.2 above, it is important to determine specifically what the "affected source" is. As mentioned above, the affected source regulated under Subpart GGG is the pharmaceutical manufacturing operation.

Pharmaceutical Manufacturing Operation

A **pharmaceutical manufacturing operation** is defined as the facility-wide collection of **pharmaceutical manufacturing process units (PMPUs)** AND any other equipment such as heat exchanger systems or cooling towers, wastewater and WMU's, that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

PMPU

A **pharmaceutical manufacturing process unit (PMPU)** is the **process**, as defined in the regulations, and any associated storage tanks, equipment identified in §63.1252(f), and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacture of a pharmaceutical product.

Process

It is important to define process, because the process vent control standards are expressed in terms of "the sum of all process vents **within a process**." A process is defined according to the pharmaceutical product or isolated intermediate it yields. An "isolated intermediate" is obtained as the product of a process and stored before subsequent processing. Storage occurs when the intermediate is put in equipment used solely for storage, such as drums, totes, day tanks, and storage tanks. Storage of an isolated intermediate marks the end of a process. The concept of process is flexible, since different pieces of equipment may be used for the manufacture of different products. For example, four pieces of equipment, A, B, C, and D, may be configured differently depending on the product being manufactured that month:

- Process 1 uses units A + C + D to yield product 1, manufactured during January
- Process 2 uses units A + C + B to yield product 2, manufactured during February

The regulations do not require, for example, that unit A meet a certain standard, but

instead that emissions from Process 1 and from Process 2 meet the regulatory standard.

The regulations contain a detailed definition of process, much of which is provided here. **Process** is defined in the regulations as "all equipment which collectively functions to produce a pharmaceutical product or isolated intermediate." The definition then goes on to add a number of other important provisions:

- A process may consist of one or more unit operations. A "process" includes any, all, or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment steps which are used to produce a pharmaceutical product.
- Cleaning operations conducted are considered part of the process.
- Nondedicated solvent recovery operations in a contiguous area are considered single processes that are used to recover numerous materials and/or products. For this use, "nondedicated" means a recovery operation that receives solvents from more than one PMPU (i.e., it is not dedicated to a single process). A storage tank used to accumulate used solvent from multiple batches of a single process for purposes of solvent recovery does not represent the end of the process. (i.e., the used solvent is not an isolated intermediate)
- Nondedicated formulation operations occurring within a contiguous area are considered a single process that is used to formulate numerous materials and/or products. Per the definition in 63.1251, "nondedicated" in this instance means the equipment is not dedicated to the manufacture of one product only.
- Quality Assurance and Quality Control laboratories are not considered part of any process.
- Ancillary activities that are not used in the processing of raw materials or in the manufacture of a pharmaceutical product are **not** covered in the definition of "process." Ancillary activities include boilers and incinerators that are not being used to comply with the MACT standards, chillers, refrigeration systems, or other pieces of equipment that operate in a closed system such that no process fluids are introduced.

IMPORTANT NOTE: As mentioned in the beginning of section 3.2, the decisions about construction and reconstruction (which affect decisions regarding "new" vs. "existing" sources) are made at the "affected facility" and/or at the PMPU level. Process vent and wastewater emissions standards must be met at the "process" or process vent level.

The definitions reviewed above are depicted in Figure 3-2.

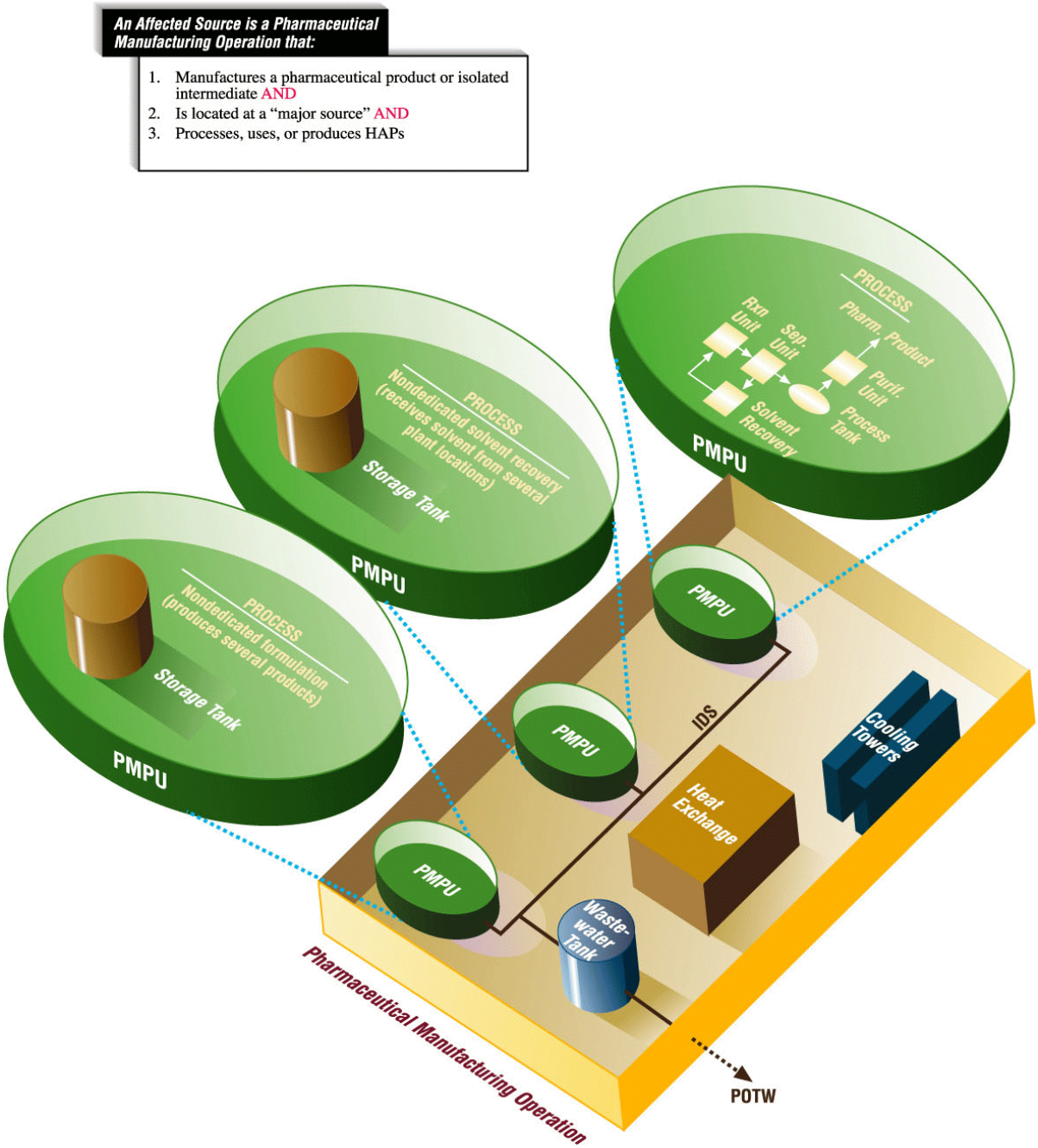


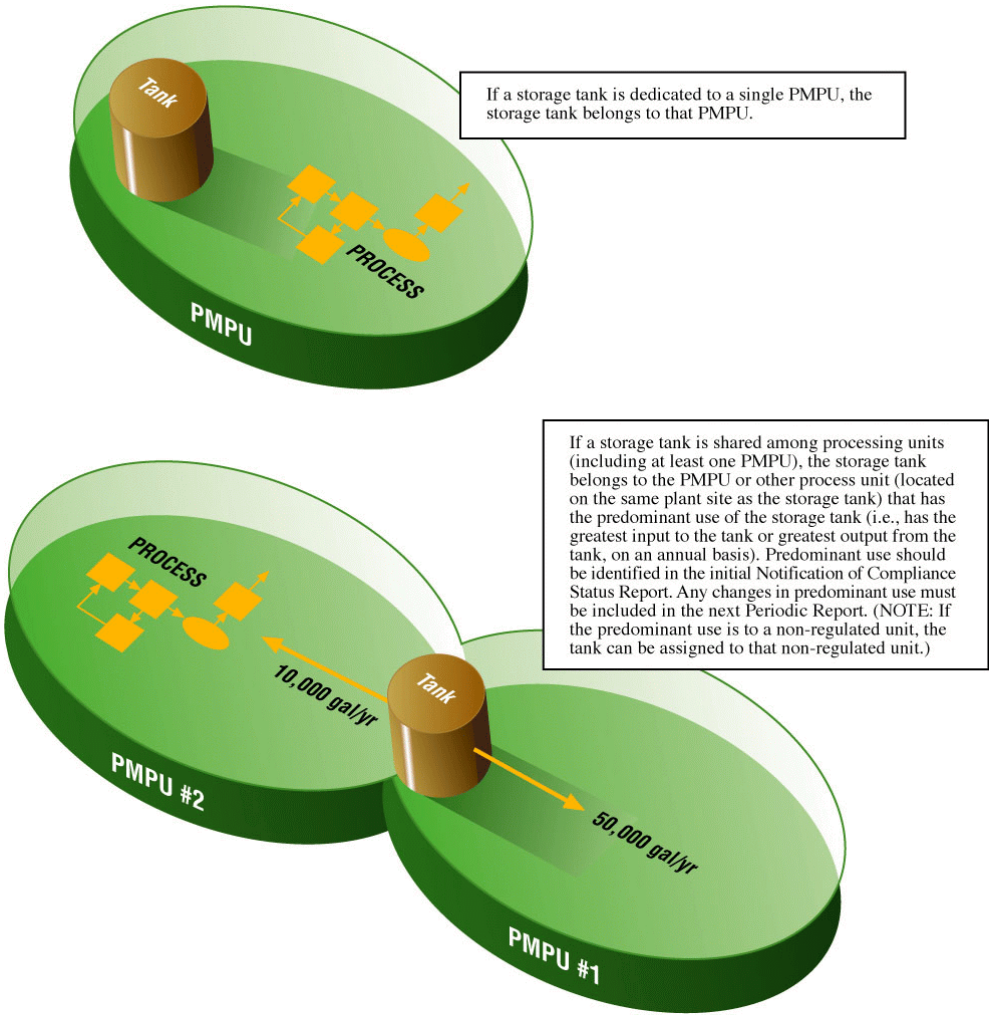
Figure 3-2. Applicability Terms

Storage Tank Ownership

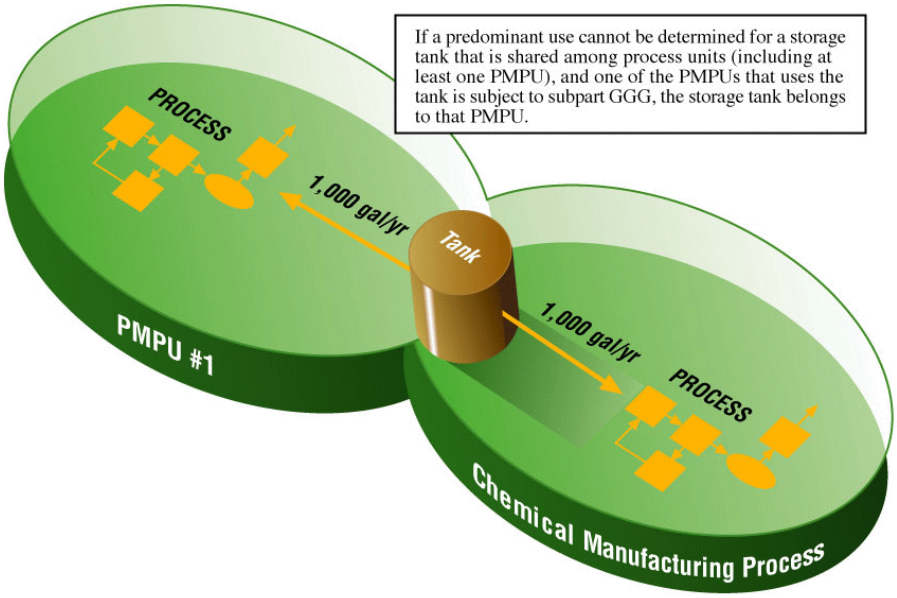
Given the variability of process configurations in pharmaceutical manufacturing plants, it is possible that storage tanks are "shared" by different PMPUs. If an owner or operator produces only pharmaceutical products, then the procedures for determining ownership are only required for purposes of determining applicability and demonstrating compliance with the P2 option, or determining new source applicability for a PMPU dedicated to manufacturing a single product that has the potential to emit 10 TPY of a single HAP or 25 TPY combined HAP.

If the owner/operator is not trying to determine the applicability of new source standards, it is not necessary to assign ownership for shared storage tanks because the tanks will be subject to the same standards regardless of ownership.

The regulations at §63.1250(e) provide the following instructions for assigning ownership of tanks:



Tank "belongs" to PMPU #1.



Tank "belongs" to PMPU #1.

If the predominant use varies from year to year, then ownership is determined according to the predominant use in the year before the rule was promulgated (i.e., the year before September 21, 1998), for existing sources. For new sources, predominant use is based on the first year after initial startup. For the first operating year at a new source, the owner or operator should base ownership decisions on the anticipated use of storage tanks. Any changes in predominant use from that reported in the Notification of Compliance Status must be reported in the next Periodic Report.

New vs. Existing

Another important applicability concept relates to the distinction between **new** and **existing** sources. EPA has the statutory authority to apply stricter standards to new sources. Also, new and existing sources may have different compliance deadlines, as discussed more fully below. In the pharmaceutical MACT regulations, the process vent and certain wastewater standards are more strict for new sources than for existing. The designation of a source as new vs. existing hinges on the date of construction or reconstruction. In summary, an affected source (PMO) for which construction or reconstruction began after April 2, 1997 is considered a new source. A PMPU that is dedicated to the production of a single product AND that has the potential to emit at least 10 tons per year of any one HAP or 25 tons per year of combined HAP AND for which construction commenced after April 2, 1997, is considered a new source. When calculating the potential to emit figure, include emissions from the PMPU and wastewater (after controls). Additionally, a reconstructed, dedicated PMPU with the potential to emit 10 tons single HAP / 25 tons combined HAP for which the fixed capital cost of the new components exceeds 50 percent of the fixed capital costs of constructing a comparable new source,

would also be considered new if the reconstruction commenced after October 21, 1999. (This date is tied to the settlement discussions after original promulgation of the rule on September 21, 1998.)

Construction and Reconstruction

The definitions of **construction** and **reconstruction** are from §63.2; they were slightly revised in the MACT rule. **Construction** means the on-site fabrication, erection, or installation of an affected source or PMPU. **Reconstruction** means the replacement of components of an affected stationary source *or pharmaceutical manufacturing process unit* to such an extent that: (1) The fixed capital cost of the new component exceeds 50 percent of the fixed capital cost that would be required to construct a comparable new source (PMPU or control device); and (2) It is technologically and economically feasible for the reconstructed source to meet the relevant standards established by the Administrator (or a State) pursuant to section 112 of the Clean Air Act.

NOTE: The addition of new equipment to an existing PMPU does not constitute construction but may constitute reconstruction if a capital expenditure occurs. The term "reconstruction" has another use besides that of defining when new sources standards are triggered. "Grandfathered" control devices (those not required to meet the 98% control standard for individual vents due to their date of installation) ARE required to meet the 98% when they are "reconstructed" or replaced.

Q and A - New vs. Existing

Q. ***If a facility with pharmaceutical operations with the potential to emit HAPs below the threshold levels for a "major source" (i.e., 10 TPY uncontrolled single HAP/25 TPY total HAP), but several new <u>non-pharmaceutical</u> processes are added at the site after April 2, 1997 such that the <u>site</u> now is above the "major source" threshold, could a pharmaceutical manufacturing operation at the site be considered new? Assume that none of the new processes have uncontrolled HAP emissions of 10 TPY single HAP/25 TPY total HAP, but that collectively they cause the site to exceed the "major source" threshold.***

A. *Upon becoming a major source, the pharmaceutical manufacturing operation is subject to the MACT standards, and must be in compliance with the standards for existing sources within three years. The PMPUs cannot be considered new because the standard was not applicable at the time of construction or reconstruction (because the PMPUs were not major sources). Even if the new processes were pharmaceutical, they still would be subject to the existing source standards, because none of the new processes individually exceed the 10 TPY/25 TPY threshold for new dedicated sources. <u>**However**</u>, if an existing area source adds a new, major-emitting dedicated PMPU (or a new area source later adds a new, major-emitting dedicated PMPU), that new PMPU must comply with the new source standards upon start-up. The existing portion of the source would be subject to the existing source standards and would have three years to comply.*

Q. ***If an existing facility adds a new piece of equipment, could it be considered a PMPU, and subject to the standards for new sources?***

A. *While it is unlikely that a single piece of equipment would constitute a PMPU, since the term PMPU applies to the "process and any associated tanks, equipment identified under §63.1252(f)...," it is possible for a single piece of equipment to be subject to new source standards. If the new piece of equipment will have potential emissions greater than 10 TPY single HAP /25 TPY total HAP, and it is dedicated to the manufacture of a single product, then the new source standards would apply.*

Q. ***If a facility adds a non-dedicated major-emitting PMPU to a plant site, but at a later date changes it to a dedicated PMPU, does that PMPU become subject to the new source standards?***

A. *If the unit was built before April 2, 1997, it could never be classified as "new," regardless of whether or not it is a dedicated unit. Even if the unit was built after April 2, 1997, changing to a dedicated process would not trigger the new source standards.*

Q. ***If a new area source (constructed or reconstructed after April 2, 1997) becomes a major source, does this trigger new source standards?***

A. *No; as with existing area sources that become major sources, a new area source that becomes a major source has three years to come into compliance with the* ***existing*** *source standards. New, major-emitting dedicated PMPUs would be subject to new source standards (see the* ***However*** *discussion in the answer above).*

Q. ***If a dedicated PMPU added to an existing source after April 2, 1997 is subject to the new source standards at the time of construction, but later changes to a non-dedicated operation, is the PMPU still required to meet the 98% control efficiency requirement?***

A. *The part of the PMPU that still that still produces the original product that made the PMPU "dedicated" would remain subject to the new source standards (i.e., 98% control efficiency). Non-dedicated PMPUs created from components of the original PMPU that are scavenged or reconfigured would be subject to the standards for existing sources. If the facility reverts back to the original process (whether dedicated or not) that triggered New Source MACT (NSM), NSM would again be applicable for that process.*

3.4 Compliance Dates

The dates by which sources must comply with the pharmaceutical MACT standards are shown below.

Type of Affected Source	Compliance Date
existing affected source (63.1250(f)(1))	**October 21, 2002***
new or reconstructed source (63.1250(f)(2)) (see below for exceptions)	**August 29, 2000,** or the date of start-up, whichever is later.
new or reconstructed source that commenced construction/reconstruction **between April 2, 1997 and September 1, 1998** (63.1250(f)(3))	**September 21, 2001**, if 1) requirements in final amendment are more stringent than those in effect before August 29, 2000 and codified in the July 1, 2000 CFR and 2) owner/operator complies with requirements published on April 2, 1997 from the later of start-up or September 21, 1998, until September 21, 2001
new or reconstructed source that commenced construction/reconstruction **between September 21, 1998 and April 10, 2000** (63.1250(f)(4))	**October 21, 2002**, if 1) requirements in final amendment are more stringent than those in effect before August 29, 2000 and 2) owner/operator complies with requirements in effect prior to August 29, 2000 from start-up until October 21, 2002
new or reconstructed source that commenced construction/reconstruction **between April 10, 2000 and August 29, 2000** (63.1250(f)(5))	**August 29, 2001,** if 1) requirements are more stringent than those published on April 10, 2000, and 2) owner/operator complies with requirements in effect prior to August 29, 2000 between start-up and August 29, 2000.

***** A 1-year extension may be granted under some circumstances. A request for an extension must be submitted no later than 120 days before the compliance date, unless the need for the compliance extension arose after that date.

3.5 Consistency with Other Regulations

There are a number of instances in which the new pharmaceutical MACT regulations may overlap other existing regulations. The regulations contain provisions relating to these areas of overlap. The following table describes what to do in these instances.

If pharmaceutical MACT regulations overlap...	Solution is to.....
Another subpart of Part 63 (63.1250(h)(1)(i))	After the compliance date, choose the subpart under which you will maintain records and submit reports to the extent the subparts are consistent. Identify the chosen subpart in the Notification of Compliance Report.
Control device monitoring, recordkeeping, and reporting requirements in RCRA subparts AA, BB, or CC (parts 264 and/or 265) (63.1250(h)(2)(i))	Choose to comply with monitoring, recordkeeping, and reporting under RCRA OR subpart GGG. If choose to comply with RCRA provisions, must report all information required in 63.1260 (g) periodic reports and (i) reports of start-up, shutdown, and malfunction. Identify in the Notification of Compliance Status report which monitoring, recordkeeping, and reporting authority will be followed.
Equipment recordkeeping and reporting requirements in RCRA subpart BB (parts 264 and/or 265) (63.1250(h)(2)(ii))	Choose to comply with the recordkeeping and reporting requirements under RCRA subpart BB OR Subpart GGG, to the extent that they overlap. Identify in the Notification of Compliance Status report if the RCRA requirements will be followed.
NSPS subpart Kb requirements for storage tanks with floating roofs (63.1250(h)(3))	Floating roofs can continue to comply with Kb - this constitutes compliance with Subpart GGG. Storage tanks with fixed roof, closed vent system, and control device subject to 40 CFR 60.112 (b) must comply with monitoring, recordkeeping, and reporting under GGG. Identify tanks in Notification of Compliance Status report that are subject to Kb.
Subpart I (63.1250(h)(4))	Choose whether to comply with Subpart H OR Subpart GGG. Identify chosen subpart in Notification of Compliance Status report. NOTE: only components subject to both Subpart I **and** GGG have the option to be regulated under GGG.
Other Part 63 requirements for offsite reloading or cleaning for storage tanks using vapor balancing (63.1250(h)(1)(ii))	Choose whether to comply with emissions standards and associated initial compliance, monitoring, recordkeeping, and reporting provisions of any other subpart of Part 63 OR with 63.1253(f)(7)(ii) or (iii). Identify in the Notification of Compliance Status Report which subpart of part 63 will be followed.
Requirements in 40 CFR Parts 260-272 (RCRA) for wastewater (63.1250(h)(5)	Owner/operator may determine whether GGG of 40 CFR 260-272 is more stringent. Compliance with the more stringent components in 40 CFR 260-272 constitutes compliance with GGG. In the Notification of Compliance Status Report, identify the more stringent provisions of 40 CFR Parts 260-272 that will be followed and explain how stringency determinations were made. If owner/operator chooses not to make stringency determinations, must comply with both 40 CFR Parts 260-272 and GGG.

If pharmaceutical MACT regulations overlap...	Solution is to.....
Subpart PPP requirements in the polyether polyols NESHAP (63.1250(h)(6))	Can choose to control all process vents according to PPP rules at 63.1425(b), (c)(1), (c)(3), (d), and/or (f) (the most stringent standards in PPP) OR identify the process vents subject to the percent reduction standards in 63.1254 and then controlling those according to the most stringent PPP standards as listed above. For those PMPUs, owner/operator must comply with rest of PPP rules (e.g., for storage tanks, wastewater, and equipment leaks). Identify in the Notification of Compliance Status report which PMPUs will be controlled under standards in PPP; include calculations used to identify which process vents are subject to percent reduction standards in 63.1254.